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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,811	12/14/2001	Rebecca E. Cahoon	BB1294 US DIV	5961

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EXAMINER	
IBRAHIM, MEDINA AHMED	
ART UNIT	PAPER NUMBER
1638	7

DATE MAILED: 03/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/021,811	CAHOON ET AL.	
	Examiner	Art Unit	
	Medina A Ibrahim	1638	

-- The MAILING DATE of this communication appears on th cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 December 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *17-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 December 2001* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 17-31 are pending and are under examination.

Sequence Listing

Applicant's CRF and paper sequence listing have been entered.

Drawings

1. The drawings filed with this application are approved by the Examiner.

Priority

This application is claiming the benefit of a prior filed nonprovisional application 09/452, 244, filed 12/01/1999, under 35 U.S.C. 120, 121, or 365(c). The specification, first line, should be amended to include the non-provisional application.

Specification

2. The disclosure is objected to because of the following informalities: for example page 12, line 3 and page 23, line 34, cite a hyperlink directed to an Internet address. The use of hyperlinks is not permitted under USPTO current policy because the content of such links are subject to a change, resulting in the introduction of New Matter into the specification. Appropriate correction is required.

Errors

The claims should be reviewed for errors. Errors appear, for example, in claim 31, part (b), and line 2, where "came" should be changed to ---same---.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the **second** paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

4. Claims 17-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 17 are indefinite because what is encompassed by "Myb-related transcriptional factor activity" is unclear. Dependent claims 18-30 are included in the rejection.

Claim 31 is indefinite because the metes and bounds of the claimed nucleotide sequences are unclear. It is unclear how the first and the second nucleotide sequences are related.

Claim 30 is indefinite because what is encompassed by the "method for isolating a polypeptide..... comprising isolating the polypeptide" is unclear". The claim fails to recite clear method steps.

Claim Rejections - 35 USC § 101

5. Claims 17-31 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible utility or a well-established utility.

The claims are drawn to an isolated polynucleotide comprising a nucleotide sequence encoding a polypeptide having at least 85%, 90% or 95% sequence identity to SEQ ID NO:36 and having Myb-related transcriptional activity, a vector, recombinant DNA construct, a plant and seed comprising said polynucleotide, and methods for transforming a cell with said polynucleotide, and isolating the polypeptide encoded by said polynucleotide. The claims are also drawn to a nucleotide sequence containing at least 60 nucleotides.

Applicant asserts that the nucleotide sequence of SEQ ID NO: 35 encoding SEQ ID NO: 36 has the utility of encoding a polypeptide having Myb-related transcription factor activity, and can be used to regulate gene expression in transgenic plants. However, based upon Applicant's disclosure, the claims do not meet the utility requirements under the current utility guidelines for the following reasons: 1) the predicted function is based solely upon sequence comparison with a known Myb protein from the prior art (see page 27, Table 1 of the specification). 2) no catalytic or DNA binding domains necessary for Myb-activity has been described, and 3) no data that relates SEQ ID NO: 36 to a Myb-related protein have been disclosed.

The specification, paragraph bridging pages 1 and 2, states that plant Myb-related proteins have been shown to involve in a diversity of plant gene expressions, including expression of disease resistance genes (WO98/13486), expression of gibberellin-regulated genes (WO97/00961), and expression of stress-related genes (WO99/16878). The specification also discloses domains that SEQ ID NO: 36 shares with the prior art Myb protein from *P. sativum* (Figure 1). However, the state of the art teaches that sequence homology alone is insufficient to determine the functional activity of a gene/protein. For example, an article from Science Journal (vol. 292, pp. 1486-1487, 2001(X)) reveals genes encoding polypeptides that share an overall secondary structure and six domains of functional importance, which are still sufficiently divergent in that their function cannot be determined by sequence similarity alone. Bork et al (Genome Research, Vol. 10, 2000, pp. 398-400 (Y)) cautions using sequence comparison to predict protein function because of known error margins for high

throughput computational methods (see page 398, columns 1-3; page 399, col.3 and paragraph bridging columns 2 and 3). Therefore, according to the article from Science Journal and Bork, sequence homology alone cannot be used to determine protein function.

While Applicants are not required to provide empirical data to verify the Myb transcriptional activity by Applicants' SEQ ID NO: 36, a functional assignment based upon sequence alignments should be a starting point for determining a particular activity of a protein and should not replace empirical verification of a tentative functional assignment. It is apparent that further research not considered to be routine would be required before one skilled in the art would know how to use Applicants' SEQ ID NO: 35 encoding SEQ ID NO: 36. Therefore, the immediate use of Applicants' SEQ ID NO: 35 encoding SEQ ID NO: 36 is unclear.

While a protein having Myb-related transcription factor activity would have substantial utility to the public, Applicants' claimed invention is not refined and developed to the point where it would have an immediate benefit to the public. Therefore, one skilled in the art cannot readily take Applicant's claimed invention and achieve the asserted utility, based upon Applicant's disclosure.

Regarding the claims drawn to polynucleotides encoding a polypeptide having at least 60%, 70%, 80%, 85%, 90% and 95% sequence identity to SEQ ID NO: 36 or a polynucleotide comprising 60 bases thereof, since SEQ ID NO: 35 encoding SEQ ID NO: 36 does not have utility as discussed above, sequences less than 100% sequence identity therefore would not have utility.

Furthermore, there is no well-established utility for the claimed SEQ ID NO: 35-36, since there is no utility for probes, primers or antibodies to the expressed gene product of a gene having no known function. Therefore, in view of the reasons set forth above, the claimed invention lacks utility.

For the reasons discussed above, one skilled in the art would not conclude that SEQ ID NO: 36 has transcription factor activity, or has utility under the current utility guidelines (see Utility Guidelines published in Federal Registry/Vol. 66, No.4/Friday, January 5, 2001/Notices; p. 1092-1099).

Claim Rejections - 35 USC § 112

Claims 17-31 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Assuming that SEQ ID NO: 35 encoding SEQ ID NO: 36 has the transcriptional factor activity of Myb, it is unclear how one skilled in the art would be able to use SEQ ID NO: 35 encoding SEQ ID NO: 36 to achieve a desired agronomic trait in a transgenic plant.

In the event that Applicant provides evidence that SEQ ID NO: 35 encoding SEQ ID NO: 36 has the transcriptional regulating activity of Myb-related proteins and can be used to induce a desired agronomic trait in transgenic plants, the enablement rejection to claims broadly drawn to isolated polynucleotides encoding a polypeptide having 80%, 85%, 90% and 95% sequence identity to SEQ ID NO: 36 and a

polynucleotide thereof comprising at least 60 bases will be maintained for the reasons as set forth below.

Applicant has not disclosed or provided sufficient guidance for how to obtain and use all of the claimed polynucleotides to produce transgenic plants having a desired phenotype. No guidance has been provided for any modifications to the disclosed sequences that resulted in polynucleotides encoding a polypeptide having at least 80%, 85%, 90% and 95% sequence identity to SEQ ID NO: 36 and a polynucleotide thereof with at least 60 nucleotides and that encode a polypeptide having the desired functional property. It is unclear which region in SEQ ID NO: 35 or 36 would tolerate modifications.

The state of the art teaches unpredictability inherent in gene/protein function if one or more base/amino acids in the gene/protein are modified. The state of the art also teaches that structural identity between two sequences (DNA or proteins) does not necessarily mean that the two sequences have similar function, even if the percent identity between the two sequences is relatively high. For example, Lazar et al (Molecular and Cellular Biology, March 1988, Vol. 8, No. 3, pp. 1247-1257 (U)) teach that a mutation of aspartic acid 47 and leucine 48 of transforming growth factor alpha results in different biological activities (see at least the Title). Broun et al (Science, 13 November 1998, vol. 282, pp. 131-133 (U)) teach that as few as four amino acid substitutions in a protein can change the protein activity (Abstract). The Examiner notes that the nucleic acid sequences encoding the proteins disclosed by either Lazar or Broun would share at least 95% sequence identity. In addition, since the only working example disclosed in the specification is limited to unmodified SEQ ID NO: 3, one

skilled in the art who is willing to practice the claimed invention is left with trial and error experimentations considered to be excessive and undue, absent specific guidance.

Therefore, given the lack of guidance, the limited working examples, state of the art, and unpredictability as discussed above, the claimed invention is not enabled throughout the broad scope.

See *Amgen Inc. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1027 (Fed. Cir. 1991) where the court held that the disclosure of a few gene sequences did not enable claims broadly drawn to any analog thereof.

Written Description

Claims 17-31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to an isolated polynucleotide comprising a nucleotide sequence encoding a polypeptide having at least 80%, 85%, 90% or 95% sequence identity to SEQ ID NO: 36 and having Myb-related transcriptional activity, a vector, recombinant DNA construct, a plant and seed comprising said polynucleotide, and methods for transforming a cell with said polynucleotide, and isolating the polypeptide encoded by said polynucleotide. The claims are also drawn to a nucleotide sequence containing at least at least 60 nucleotides said nucleotide sequences.

The claimed invention does not meet the current written description requirements because Applicant has not described a single variant having the structural and

functional properties as recited in the claims. Applicant only describes SEQ ID NO: 35 and a nucleotide sequence encoding SEQ ID NO: 36. The disclosure of SEQ ID NO: 35 does not provide adequate written description for all polynucleotides encoding a polypeptide having at least 80%, 85%, 90% or 95% sequence identity to SEQ ID NO:36 or any and all nucleotide sequences with at least 60 nucleotides in length comprised by said polynucleotides. Substantial variation in structures and function are expected among polynucleotides that share 60 non-contiguous bases. Since Applicant has not described a single variant encoding a polypeptide having the structural and functional properties as recited in the claims, one skilled in the art would know from the disclosure that Applicant is in possession of the invention as broadly claimed. Therefore, the written description requirement is not satisfied. Since Applicant has not described the polynucleotide of claims 17-22 and 31, the expression vector, the plant, the seed, and the cell comprising the polynucleotide are similarly not described.

See Written description Examination Guidelines published in Federal Registry/Vol. 66, No.4/Friday, January 5, 2001/Notices). See, also *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (Fed. Cir. 1997).

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> *A person shall be entitled to a patent unless –*
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim 31 is rejected under 35 U.S.C. 102(b) as being anticipated by Iturriaga et al (Accession no. U33917, pages 6-7 of the Sequence Search Result).

The claim is drawn to an isolated polynucleotide comprising a first nucleotide sequence containing at least 60 nucleotides, said first nucleotide sequence is comprised by another polynucleotide sequence encoding a polypeptide having Myb-related transcription factor activity and having at least 80% sequence identity to SEQ ID NO: 36 or the fully complement of said another polynucleotide. The claim is interpreted to encompass a polynucleotide comprising a nucleotide sequence of at least 60 nucleotides of a nucleotide sequence encoding a polypeptide having Myb-related activity and having at least 80% sequence identity to SEQ ID NO: 36 or the fully complement of said nucleotide sequence.

Iturriaga et al teach an isolated nucleotide sequence encoding a polypeptide having Myb transcription factor activity and having at least 60 nucleotides of SEQ ID NO: 35 (see attached Sequence Search Result, pages 5-6). Since the claim does not require that the 60 nucleotides be contiguous, any nucleotide sequence encoding a polypeptide having Myb-related activity and having at least 80% sequence identity to SEQ ID NO: 36 or the fully complement of said nucleotide sequence would inherently comprising the claimed 60 nucleotides.

Remarks

The nucleotide sequence of SEQ ID NO: 35 and nucleotide sequence encoding SEQ ID NO: 36 are free of the prior art of record.

No claim is allowed.

Papers related to this application may be submitted to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1638, using fax number (703) 308-4242. All Technology Sector 1 fax machines are available to receive transmission 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Medina A. Ibrahim whose telephone number is (703) 306-5822. The Examiner can normally be reached Monday-Thursday from 8:30AM to 5:30PM and every other Friday 9:00AM to 5:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

3/3/03
Mai

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